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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/963,759 | 09/25/2001 | Philip R. Andersen | 00088-008004 | 2138 |
| 26161 7590 01/22/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | EXAMINER PENG, BO | |
| | | | ART UNIT 1648 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/22/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/963,759 | | ANDERSEN ET AL. | |
| | Examiner | | Art Unit | |
| | Bo Peng | | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-19, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17-19, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on November 6, 2006 has been entered.

3. Applicant's amendment filed on September 26, 2006 is acknowledged. Claims 14, 17 and 19 are amended.

4. Accordingly, Claims 14-19, 22 and 23 are pending. Claims 15 and 16 are withdrawn from consideration. Claims 14, 17-19, 22 and 23 are considered in this Office action.

5. The objection to the specification is **withdrawn** in view of the amendment to the specification.

6. The objection of Claims 22 and 23 under 37 CFR 1.75 as being substantial duplicates of Claims 17 and 18, is **withdrawn** in view of Applicant's amendment.

7. The rejection of claims 14, 17-19, 22, and 23 under 35 U.S.C. under 35 U.S.C. § 102(e)

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as being anticipated by Pedersen et al. (5,565,319), **is maintained**.

8. The instant claims are drawn to a method for detecting FIV infection comprising contacting FIV envelope polypeptide in a mixture comprising the polypeptide that reacts with envelope protein-binding antibodies in a sample and assay device comprising an isolated FIV envelope polypeptide, wherein the isolated polypeptide lacks components of cells in which the virus occurs (emphasis added indicating the amended part).

9. Applicant argues that the amended Claims 14 and 19 require that the polypeptide lacks components of cell in which the virus occurs. However, The infected cell lysate of Fig. 4 of Pedersen's reference would include components of cells in which the virus occurs (Remarks).

10. Applicant's argument is considered, but found unpersuasive for following reasons: Pedersen's teach is not limited by his Figure 4. Pedersen also teaches that the FTLV (FIV) polypeptides may be natural, i.e., including the entire FTLV (FIV) protein or fragments thereof isolated from a natural source, or may be synthetic (Paragraphs 5 and 6, Column 4). Pedersen teaches synthetic polypeptides may be synthesized by the well-known Merrifield solid-phase synthesis method where amino acids are sequentially added to a growing chain. Pedersen teaches that FTLV (FIV) polypeptides can be used in various immunological techniques for detecting FTLV (FIV) and anti-FTLV(FIV) antibodies in physiological specimens, particularly body fluid samples, including blood, plasma, serum, urine, and the like, and cell samples, such as lymphocytes (see line 66, column 6, to line 5, column 7).

11. Since Pedersen teaches the application of FIV peptides, prepared either from nature sources or by chemical synthesis, for detecting FIV or FIV antibody in a mixture, and it is known that the synthetic polypeptide made by Merrifield solid-phase synthesis method "lacks

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components of cells in which the virus occurs”, Pedersen anticipates the instantly claimed invention.

New Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 14 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. Please note that the scope of newly amended Claims 14 and 19: “wherein the isolated polypeptide lacks components of cells in which the virus occurs” is NEW MATTER. A survey of the specification failed to find such limitation. Removal of all new matter is required. *In re Russmussen* 210 USPQ 325.

15. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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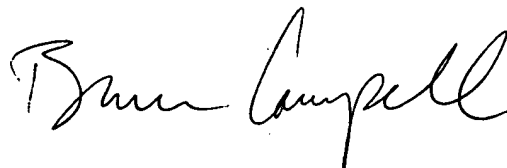
applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
January 9, 2007



BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600